510(k) Summary of Safety and Effectiveness

Ivoclar Vivadent, Inc.
175 Pineview Dr., Amherst, NY 14228
Tel: 716-691-0010 Fax: 716-691-2294

K062258

Donna Hartnett,
Preparation Date: June 27, 2006

Device Name:

Trade Name:	Odyssey Navigator Diode Laser
Common Name:	810nm Diode Laser
Product Classification:	Laser, Dental, Soft Tissue

MAR 2 1 2007

Legally Marketed Predicate Devices for Substantial Equivalence:

Odyssey 2.4G Diode Laser, Manufactured by Ivoclar Vivadent, Inc.

SiroLaser, Manufactured by Sirona Dental Systems, Gmbh

Rationale for Substantial Equivalence:

The aforementioned laser devices and their accompanying delivery systems share similar indications for use in the oral environment, similar design features including wavelength, operating controls, and laser delivery method. The devices share similar methods of control systems, safety features, and performance monitoring. The devices share similar performance specifications including power output and energy type.

Description of Submitted Device:

The Odyssey Navigator Diode Laser is a portable device for delivering laser energy to surfaces within the oral cavity. This energy is generated by solid-state diodes, which provide a consistent and reliable generation of laser energy at 810 ± 20nm for a maximum of 3 watts of energy output. The laser energy is delivered to the surgical site by means of a proprietary optical fiber system, which allows for the safe transmission of laser energy to the site without creating undue risk to the patient or operatory staff by errant or collateral laser emissions. The device features some user definable settings, including a switchable 650nm aiming beam, adjustable power output for both the working beam and aiming beam, and continuous delivery or pulse delivery option.

The working end of the delivery fiber is a disposable single-use tip which is attached to a metal autoclavable handpiece. This handpiece system is provided with the device. The fiber tip attachment assembly is delivered sterilized in individual mylar blister packages. Sterlization is accomplished by Irradiation.

The activation of the working beam diodes is completed by use of a foot-actuated switch.

Intended Uses of the Odyssey Navigator Diode Laser: The device is intended to be used for a variety of surgical procedures on soft tissue within the oral cavity including:

Dental, oral, and soft tissue surgery including:

- Sulcular debridement of diseased or fibrous tissue
- Excision and biopsy
- Gingivectomy and gingivoplasty
- Lesion (tumor) removal
- Fibroma removal
- Tissue retraction (troughing)
- Aphthous ulcers
- Gingival hyperplasia (excision and recontour)
- Crown Lengthening
- Operculectomy
- Frenectomy
- Photocoagulation

Laser Periodontal procedures, including:

- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Removal of inflamed edematous tissue.

Technological Characteristics and Substantial Equivalence:

The Odyssey 2.4G uses solid state diodes to generate laser energy in the 810nm range. This system uses a fiber delivery system to transmit laser energy to the surgical site. The system also features a 650nm adjustable output aiming beam and features controls that allow for adjusting the output of the working beam, and switching between a continuous or pulsed-mode laser emission. The maximum output of the unit 5 watts.

The SiroLaser utilizes solid-state diode lasers to generate laser energy in the 980nm range. The power range is from 0.5 – 7.0 watts and operates in continuous or pulse mode. The system utilizes an optical fiber to transmit laser energy from the control unit to the work site. The distal end of the fiber is contained with a metal handpiece and terminates in a disposable handpiece tip. The system features an LCD touchscreen to access the controls and features of the system.

Performance Standards:

The Odyssey Navigator Diode Laser complies with the performance requirements of 21 CFR 1040.10 and 1040.11, with permissible deviations relative to Laser Notice 50, dated July 26, 2001. The device also complies with IEC 60601-1:1998+A1+A2, IEC 60601-2-22:1995, and IEC 60825-1:1993+A1+A2.

Clinical Performance Data

	Ivoclar Vivadent, Inc. Odyssey Navigator Diode Laser	Ivoclar Vivadent, Inc. Odyssey 2.4G Diode Laser	Sirona Dental Systems, Gmbh SiroLaser
Wavelength	810±20 nm	810±20 nm	980 nm
Power	0.1 - 3.0 watts	0.1 – 5.0 watts	0.5 – 7.0 watts
Aiming Beam	630-650 nm, 2mW	630-650 nm, 3mW	630-680 nm, power unavailable
Cooling System	Fan air cooled	Fan air cooled	Fan air cooled
Pulse Control	Digital emission control	Digital emission control	Digital emission control
Laser Source	Solid-state diode	Solid-state diode	Solid-state diode
Power Requirements	100-240 VAC @ 50-60 Hz, 0.5A (switchable)	100-240 VAC @ 50-60 Hz, 1.5A (switchable)	unknown
Dimensions	7" x 4" x 2-3/8"	10" x 8" x 4"	7.5" x 3.5" x 2-1/8"
Weight	1 lb, control unit only	6.5 lbs	1 lb, control unit only
User Interface	LCD Touch Screen	LED Display, Membrane Touch Pad	LCD Touch Screen
510(k) Number	Pending this applicaiton	K050453	K053161

Conclusion

The Odyssey Navigator Diode Laser is substantially equivalent to the listed laser surgical devices without raising any issues of safety or effectiveness. This device shares similar intended uses, and similar functional and performance characteristics. The device is designed to comply with relevant federal and international safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ivoclar Vivadent, Inc.
% Ms. Donna Marie Hartnett
Director QA/Regulatory Affairs
175 Pineview Drive
Amherst, New York 14228

MAR 2 1 2007

Re: K062258
Trade/Device Name: Odyssey Navigator Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 5, 2007
Received: March 6, 2007

Dear Ms. Hartnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062258

Device Name: Odyssey Navigator Laser

Indications For Use:

Dental, oral, and soft tissue surgery including:
Sulcular debridement of diseased or fibrous tissue
- Excision and biopsy
- Gingivectomy and gingivoplasty
- Lesion (tumor) removal
- Fibroma removal
- Tissue retraction (troughing)
- Aphthous ulcers
- Gingival hyperplasia (excision and recontour)
- Crown Lengthening
- Operculectomy
- Frenectomy
- Photocoagulation

Laser Periodontal procedures, including:

- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Removal of inflamed edematous tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062258